

Docket No. SA-539

Exhibit No. 18-A

NATIONAL TRANSPORTATION SAFETY BOARD

Washington, D.C.

MEDICAL FACTUAL REPORT

(19 Pages)



NATIONAL TRANSPORTATION SAFETY BOARD

Office of Research and Engineering
Washington, DC

MEDICAL FACTUAL REPORT

December 2, 2016

Nicholas Webster, MD, MPH
Medical Officer

A. ACCIDENT: DCA16MA204 - Lockhart, Texas

On July 30, 2016, at about 0742 central daylight time, a Balony Kubicek BB85Z hot air balloon, registration N2469L, crashed into a field after striking high voltage powerlines near Lockhart, Texas. The 15 passengers and pilot were fatally injured and the balloon was substantially damaged due to impact forces and post-crash fire. The flight was operating under 14 *Code of Federal Regulations* Part 91 as a commercial sightseeing passenger operation.

B. GROUP IDENTIFICATION:

No group was formed to evaluate the pilot medical issues.

C. RELEVANT REGULATIONS

Per Title 14 Code of Federal Regulations 61.23 (b), A person is not required to hold a medical certificate

(3) When exercising the privileges of a pilot certificate with a glider category rating or balloon class rating in a glider or a balloon, as appropriate.

Therefore, the balloon pilot was not required to have a medical certificate to operate as a commercial balloon pilot. However, all certificated pilots are required to refrain from performing any flight crew duties when they are medically unable to perform safely, even if they are not required to hold a valid medical certificate. 14 CFR 61.53, Prohibition on operations during medical deficiency states,

(b) *Operations that do not require a medical certificate.* For operations provided for in § 61.23(b) of this part, a person shall not act as pilot in command, or in any other capacity as a required pilot flight crewmember, while that person knows or has reason to know of any medical condition that would make the person unable to operate the aircraft in a safe manner.

According to the Federal Aviation Administration's (FAA) "Do Not Issue –Do Not Fly" instructions, included in its Guide for Aviation Medical Examiners, pilots who report "regular or intermittent use of any drug or substance classified under the Controlled Substances Act (Schedules I - V)" should not be issued a medical certificate. Additionally, it states that airmen should not fly while using any medications listed in schedule I-V as well as mood stabilizers, most antidepressants, ADD or ADHD medications, sedative hypnotics and tranquilizers. The list specifically includes diphenhydramine, oxycodone, and cyclobenzaprine.¹

In addition, pilots are held to stricter drug and alcohol limits than drivers. Per 14 CFR 91.17,

- (a) No person may act or attempt to act as a crewmember of a civil aircraft² —
 - (1) Within 8 hours after the consumption of any alcoholic beverage;
 - (2) While under the influence of alcohol;
 - (3) While using any drug that affects the person's faculties in any way contrary to safety; or
 - (4) While having an alcohol concentration of 0.04 or greater in a blood or breath specimen. Alcohol concentration means grams of alcohol per deciliter of blood or grams of alcohol per 210 liters of breath.

Finally, all certificated pilots are required to report convictions for driving offenses related to drugs or alcohol to the FAA within 60 days. Specifically, per 14 CFR Part 61.15, Offenses involving alcohol or drugs

c) For the purposes of paragraphs (d), (e), and (f) of this section, a motor vehicle action means:

- (1) A conviction after November 29, 1990, for the violation of any Federal or State statute relating to the operation of a motor vehicle while intoxicated by alcohol or a drug, while impaired by alcohol or a drug, or while under the influence of alcohol or a drug;
- (2) The cancellation, suspension, or revocation of a license to operate a motor vehicle after November 29, 1990, for a cause related to the operation of a motor vehicle while intoxicated by alcohol or a drug, while impaired by alcohol or a drug, or while under the influence of alcohol or a drug; or
- (3) The denial after November 29, 1990, of an application for a license to operate a motor vehicle for a cause related to the operation of a motor vehicle while intoxicated by alcohol or a drug, while impaired by alcohol or a drug, or while under the influence of alcohol or a drug.

(d) Except for a motor vehicle action that results from the same incident or arises out of the same factual circumstances, a motor vehicle action occurring within 3 years of a previous motor vehicle action is grounds for:

- (1) Denial of an application for any certificate, rating, or authorization issued under this part for a period of up to 1 year after the date of the last motor vehicle action; or
- (2) Suspension or revocation of any certificate, rating, or authorization issued under this part.

¹ FAA Guide for Aviation Medical Examiners. Pharmaceuticals (Therapeutic Medications) Do Not Issue - Do Not Fly. https://www.faa.gov/about/office_org/headquarters_offices/avs/offices/aam/ame/guide/pharm/dni_dnf/ Accessed 11/16/2016.

² 49 USC 40102 defines a civil aircraft as an aircraft except a public aircraft – a balloon is a civil aircraft.

(e) Each person holding a certificate issued under this part shall provide a written report of each motor vehicle action to the FAA, Civil Aviation Security Division (AMC-700), P.O. Box 25810, Oklahoma City, OK 73125, not later than 60 days after the motor vehicle action. The report must include:

- (1) The person's name, address, date of birth, and airman certificate number;
- (2) The type of violation that resulted in the conviction or the administrative action;
- (3) The date of the conviction or administrative action;
- (4) The State that holds the record of conviction or administrative action; and
- (5) A statement of whether the motor vehicle action resulted from the same incident or arose out of the same factual circumstances related to a previously reported motor vehicle action.

(f) Failure to comply with paragraph (e) of this section is grounds for:

- (1) Denial of an application for any certificate, rating, or authorization issued under this part for a period of up to 1 year after the date of the motor vehicle action; or
- (2) Suspension or revocation of any certificate, rating, or authorization issued under this part.

D. DETAILS OF INVESTIGATION

Purpose

The investigation evaluated the pilot for medical conditions, the use of medications or illicit drugs, and the presence of any toxins. Additionally, the investigation evaluated regulatory oversight of pilots with medical conditions, criminal convictions, and drug or alcohol misuse or abuse.

Methods

The pilot's FAA medical certification file, FAA medical case review, FBI criminal history, Missouri driving records, FAA AMC-700 letter to pilot, personal medical records, autopsy report, and toxicology reports were reviewed.

FAA Medical Certification File and FAA Medical Case Review

According to the FAA medical certification records, the 49-year-old male pilot had one medical certification examination, dated July 29, 1996. At that time, he measured 71 inches tall, weighed 227 pounds, and reported he had accrued 300 total flight hours. He reported no medical conditions and no medications. In addition, he marked "no" to all items in section 18 including: 18v, "conviction and/or administrative history of driving while impaired or intoxicated" and 18w, "history of nontraffic conviction(s) (misdemeanors or felonies)." The aviation medical examiner marked "normal" next to all items on the physical examination and issued the pilot a third class medical certificate with no limitations.

According to a memorandum in the medical certification file from the Security and Hazardous Material Organization to the Civil Aerospace Medical Institute (AAM-313), dated July 22, 2013, the FAA security office had identified five separate alcohol related driving convictions and license actions for the pilot.³ (See Attachment 1.) Notably, the first of these occurred prior to the pilot's application for a medical certificate. Additionally, it documented chemical refusals on February 8, 1997; December 11, 1999; April 1, 2000;

³ FAA AMC-700 is the FAA office of Security and Hazardous Materials Safety. It investigates and manages the legal and administrative requirements as set forth in 14 CFR 61.15.

and June 16, 2007. The memorandum stated “The following action has been initiated by AMC-700: ***No Enforcement Action - Notification Letter.***”

FAA AMC-700 Letter to Pilot

The investigation obtained a copy of the notification letter from AMC-700 to the pilot dated July 29, 2013. The letter included the following statement “...***We have decided not to take legal enforcement action. Instead, we are issuing this letter to inform you that future violations of the CFRs could result in suspension and/or revocation of your airman certificate. When completing your next Application for an Airman Medical Certificate, FAA Form 8500-8, please read Question 18v carefully and follow the instructions attached when answering the question. Question 18v seeks information regarding arrests, convictions, and/or administrative actions (such as, driver license suspensions, cancellations, revocations, denials) or loss of driving privileges, and any required attendance at a substance abuse program or an alcohol education or rehabilitation class.***”

Criminal History and Driving Record

According to FBI National Crime Information Center records and Missouri driving records, the pilot had multiple arrests, convictions, and incarcerations. Additionally, at the time of the accident the balloon pilot did not have a valid Missouri driver’s license and was not eligible to obtain a license until 2020. A historical summary was provided by the NTSB Senior Advisor Special Operations and Interagency Coordination, and included the following:

- 1987 - Arrested twice, possession of drugs - Felony
 - Given 3 years of probation starting October 1987
 - Completed drug counseling
- 1996 - Interfering with an arrest - Misdemeanor
- 1998 - Driving While Intoxicated (DWI) /Alcohol and possession of a controlled substance - Felony
- 1999 - Possession of a controlled substance - Felony
- 1999 - Distribution and delivery of manufactured substance ⁴
 - Convicted and sentenced for 10 years August 2002
- 2000 - DWI/Alcohol "persistent offender"
 - Sentenced to 1 year, guilty as of September 2002
 - Incarcerated from October 2002 to April 2004
- 2007 - Leaving the scene of an accident and operating with suspended Driver’s License (DL)
- 2010 - DWI/Alcohol “aggravated offender” and driving with a revoked DL
 - DL revoked until 2020
 - Incarcerated July 10, 2010 - released into probation on January 28, 2012
 - Complete release (finished jail and probation period) as of August 26, 2013

Personal Medical Records

The investigation received medical records from two different locations: The South County Health and Medical Services Clinic in Saint Louis, Missouri, which provided primary care psychiatric and counseling services; and a physician’s office in Kyle, Texas where the pilot

⁴ At the time of this report, the investigation had not identified the specific controlled substance associated with the pilot’s convictions.

had received primary care services. The records dated from June 2013 to July 28, 2016 (2 days before the accident). Review of records from both locations identified the following active diagnoses: alcohol dependence in remission since 2007; high blood pressure and elevated cholesterol treated with losartan and simvastatin respectively; type 2 diabetes first diagnosed in 2002, treated with the oral medication metformin and injectable insulin; major depressive disorder diagnosed in 1990, treated with bupropion and fluoxetine; attention deficit disorder, diagnosed in childhood, treated with methylphenidate; insomnia, diagnosed in 2007, treated with zolpidem; fibromyalgia diagnosed in 1990 treated with cyclobenzaprine, piroxicam, and pregabalin; and chronic back pain with muscle spasm, diagnosed in 2007, treated with oxycodone and diazepam. Table 1 summarizes the pilot's active medical conditions and medications, Table 2 summarizes his health care visits over the year preceding the accident, and Table 3 summarizes his prescriptions during that year. Additional information about drugs and drug interactions identified during the investigation can be found in the toxicology section of this report.

Table 1. Pilot's Active Medical Conditions and Medications

Medical Condition	Medication *
Alcohol dependence - remission	None
High blood pressure	Losartan
Elevated cholesterol	Simvastatin
Diabetes – type 2	Insulin
	Metformin
Major depressive disorder	Bupropion
	Fluoxetine
Attention deficit disorder	Methylphenidate
Insomnia	Zolpidem
Fibromyalgia	Cyclobenzaprine
	Piroxicam
	Pregabalin
Chronic back pain / spasm	Oxycodone
	Diazepam

* For additional medication information see Table 3 Pilot's Most Recent Prescription Medications

Table 2 - Pilot's Identified Health Care Visits Over Year Preceding the Accident

Provider	State	Diagnosis	Prescribed Medications	Date Visited
Primary Care	TX	Chronic pain	Oxycodone	July 28, 2016
			Diazepam	
		Attention Deficit Disorder	Methylphenidate	
Primary Care	MO	Fibromyalgia	Piroxicam	Apr 26, 2016
			Pregabalin	
			Cyclobenzaprine	
		High blood pressure	Losartan	
		High cholesterol	Simvastatin	
		Diabetes	Insulin	
	Metformin			
Psychiatry	MO	Major Depression	Bupropion	April 25, 2016
			Fluoxetine	
			Zolpidem	
Primary Care	TX	Chronic Pain	Oxycodone	Apr 12, 2016
			Diazepam	
		Attention Deficit Disorder	Methylphenidate	
Primary Care	MO	Refill Arrived	None	Jan 14, 2016
Primary Care	TX	Chronic Pain	Oxycodone	Dec 10, 2015
			Diazepam	
		Insomnia	Zolpidem	
		Attention Deficit Disorder	Methylphenidate	
Primary Care	MO	Neuropathy	Pregabalin	Dec 01, 2015
Primary Care	MO	Fibromyalgia	Piroxicam	Oct 27, 2015
			Pregabalin	
			Cyclobenzaprine	
		High Blood Pressure	Losartan	
		High Cholesterol	Simvastatin	
		Diabetes	Insulin	
	Metformin			
Primary Care	MO	Diabetes	Insulin	Sept 18, 2015
Psychiatry	MO	Major Depression	Bupropion	Jun 19, 2015
			Fluoxetine	
			Zolpidem	
Primary Care	MO	Fibromyalgia	Piroxicam	Jun 17, 2015
			Pregabalin	
			Cyclobenzaprine	
		High Blood Pressure	Losartan	
		High Cholesterol	Simvastatin	
		Diabetes	Insulin	
	Metformin			
Primary Care	TX	Chronic Pain	Oxycodone	May 11, 2015
			Cyclobenzaprine	
			Diazepam	
		Insomnia	Zolpidem	
		Attention Deficit Disorder	Methylphenidate	

Table 3 – Pilot's Most Recent Prescription Medications

#	Medication	Dose / Days Supplied	Description (Trade Name)	DEA* Schedule	Provider Type / State	Date Filled
1	Losartan	25 mg, one daily / 30 days	Blood pressure (Cozaar)	None	Primary Care MO	July 25, 2016
2	Simvastatin	40 mg, one daily	Cholesterol lowering medication (Zocor)	None	Primary Care MO	July 25, 2016
3	Metformin	1000 mg, one twice daily / 30 days	Oral diabetes medication (Glucophage)	None	Primary Care MO	July 25, 2016
4	Insulin –long and short acting	55 units long acting daily, 15 units short acting twice daily / 30 days	Injected diabetic medication used to regulate blood sugar	None	Primary Care MO	July 2016 Mail order - Exact date not determined
5	Piroxicam	20 mg, one daily / 30 days	Non-sedating medicine used to treat pain and inflammation (Feldene)	None	Primary Care MO	July 25, 2016
6	Fluoxetine***	20 mg, four daily / 30 days	Antidepressant medication (Prozac)	None	Psychiatry MO	July 25, 2016
7	Bupropion XL**	300 mg, one daily / 30 days	Antidepressant medication (Wellbutrin XL)	None	Psychiatry MO	July 25, 2016
8	Cyclobenzaprine	10 mg, one twice daily / 30 days	Sedating muscle relaxant (Amrix)	None	Primary Care MO	June 27, 2016
9	Zolpidem	10 mg, one at bedtime / 90 days	Sedating short acting sleep aid (Ambien)	Schedule IV	Primary Care MO	June 27, 2016
10	Methylphenidate	10 mg, one in morning, two at night / 30 day	Central nervous system stimulant used to treat ADHD and narcolepsy (Ritalin)	Schedule II	Primary Care TX	June 19, 2016
11	Oxycodone	5 mg, one twice daily / 30 day	Sedating opioid pain medication (OxyContin)	Schedule II	Primary Care TX	June 19, 2016
12	Diazepam	10 mg, one twice daily / 30 day	Sedating benzodiazepine for anxiety and muscle spasms (Valium)	Schedule IV	Primary Care TX	June 19, 2016
13	Pregabalin	200 mg, one twice daily / 90 day	Sedating anticonvulsant drug for seizures and nerve pain (Lyrica)	Schedule V	Primary Care MO	May 23, 2016

* The Drug Enforcement Agency identifies drugs and other substances that are considered controlled substances under the Controlled Substances Act and divides them into five schedules. Substances are placed in their respective schedules based on whether they have a currently accepted medical use in treatment in the United States, their relative abuse potential, and likelihood of causing dependence when abused. Schedule II substances have a high potential for abuse while schedule V substance have a low potential for abuse.

** The investigation reviewed available clinical and pharmacy records and determined that over the past year, the pilot had regularly refilled his identified prescribed medications. However, there was no evidence he had filled his fluoxetine or bupropion prescriptions in February, March, or May of 2016.

Texas Primary Care Records

According to records from his Texas primary care provider the patient's first visit was January 28, 2014 and his last visit was July 28, 2016 (*2 days before the accident*). On that day, height and weight were not recorded. The patient reported he was generally doing well but complained of continued fibromyalgia symptoms and low back pain. He requested refills of oxycodone for the pain and methylphenidate for his attention deficit disorder. The Texas physician was aware of the patient's ongoing care by physicians in Missouri. The investigation found no evidence that the Texas primary care provider was aware that the patient was an active commercial balloon pilot.

Missouri Primary Care Records

According to records from his Missouri primary care provider, the patient's last visit was April 26, 2016. On that visit his recorded height was 72 inches, weight was 270 pounds, and body mass index was 36.7 kg/m².⁵ The reason for the clinic visit was "medication refills" and the physician documented his type II diabetes was being treated with insulin and metformin; laboratory results recorded a serum glucose of 186 and hemoglobin A1C of 7.0.⁶ The last eye exam had been about one year prior and identified no diabetic changes. The physician documented good compliance with diabetic treatment and did not mention any side effects from the diabetes or its treatment. Additionally, the patient complained of ongoing fibromyalgia symptoms including muscle and joint pain, generalized fatigue and widespread pain described as moderate in severity but unchanged. He was prescribed pregabalin, piroxicam, and cyclobenzaprine.⁷ Finally, the provider documented the patient was compliant with his medication for high blood pressure and elevated lipids and recorded there was good symptom control. The file did not contain any documentation the Missouri primary care provider was aware of ongoing treatment in Texas. Additionally, the investigation found no evidence that the Missouri primary care provider was aware the patient was an active commercial balloon pilot.

Missouri Mental Health Records

Psychiatric care records from Saint Louis, Missouri included eight psychiatrist visits from November 15, 2013 to April 25, 2016. The patient was diagnosed with major depressive disorder plus dysthymic disorder, attention deficit disorder, insomnia, and alcohol dependence in full remission since 2007. According to the last psychiatric visit, dated April 25, 2016, he had major depressive disorder but had not been using his medications for three months. He had had recurrent symptoms of poor sleep, low mood, poor motivation, social isolation, and irritability. The mental status exam documented the patient's mood as "not good," affect was described as expansive and broad, but identified no suicidal or homicidal ideation. The impression of the examining physician was major depressive disorder with diabetes and fibromyalgia, along with the possibility of attention deficit hyperactivity disorder (ADHD). The health care provider restarted the antidepressant medications fluoxetine and bupropion, and the short acting prescription sleep-aid zolpidem. The investigation found no evidence that the treating psychiatrist was aware the patient was an active commercial balloon pilot.

⁵ According to the National Institute of Health a BMI of over 35 kg/m² indicates obesity and increase the risk of Type II diabetes, high blood pressure and cardiovascular disease.

⁶ See the medical conditions section of this report for further explanation of the pilot's diagnosed medical conditions.

⁷ For additional information on medications see Table 3 Pilot's Most Recent Prescription Medications.

The only identified psychiatric testing report was dated November 5, 2013 and had been performed to evaluate the patient's complaints of difficulty with attention, memory and organization. The report recorded "***He has a history of depression, alcohol and substance abuse. He has a pilot license and work for a hot air balloon company, but suffered a severe back injury in 2007, and is unable to fly. He now works in reservations but often makes errors due to distractibility and forgetfulness.***" The record documented that the patient was prescribed methylphenidate and had taken the medication the morning of the evaluation. The evaluation included the following results of testing:

- Responses to the WHO-Self Report Scale Symptom Checklist indicated that he was highly likely to have ADHD, for both the inattentive and the hyperactive-impulsive section of the questionnaire.^{8,9}
- His ability for short-term auditory memory was poor, with a scaled score of six (deficient range) on the Digit Span test. His speed of task execution was in the low average, with a scaled score of seven on the Symbol Search test.^{10,11}
- His perceptual-motor integration skills, as measured by the Rey-Osterrieth Complex Figure test, were average, with a scaled score of 10 for the copy of the figure. His ability for recall was quite good. His style however, was rather impulsive, and he tended to overlook details, and to lack accuracy.^{12,13}
- On the Rey Auditory and Verbal Learning Test, [his] overall performance placed him within the average range, with a standard score of 95. He was observed to be easily distracted during testing, and to repeatedly mention the word "cow" which was not in the list of fifteen unrelated words read to him.^{14,15}

The psychologist's diagnostic impression was ADHD, combined type, depressive disorder, as well as alcohol and substance abuse, in remission. Additionally, the provider concluded the tests were valid and indicated difficulties with attention, concentration, and recall of verbal information. Finally, the psychologist documented that the client had used methylphenidate on the morning of the test and his current prescription regime did not appear to effectively control ADHD symptoms.

The pilot's mental health records also included details from four sessions with a mental health counselor between June and July 2013. During these sessions, the counselor worked with the client to manage his anxiety, depression, inability to focus, interpersonal relationships, and managing the effects of fibromyalgia. Additionally, the patient reported concern that the FAA and his insurance company found out about his felony charges and DWI and he was working with a hot-air balloon company. On June 17, 2013, the record documented the client was alcohol dependent, had been sober for 6 months, and was

⁸ WHO-Self Report Scale Symptom Checklist is a test to help identify ADHD.

⁹ Kessler RC et al. The World Health Organization adult ADHD self-report scale (ASRS): a short screening scale for use in the general population. *Psychological Medicine*, 2005, 35, 245–256

¹⁰ The Wechsler Adult Intelligence Scale-Fourth Edition is a test to assess the cognitive ability of adults

¹¹ Conway AR et al. Working memory span tasks: A methodological review and user's guide, *Psychonomic Bulletin & Review* 2005, 12 (5), 769-786

¹² The Rey–Osterrieth Complex Figure Test is a neuropsychological test for the evaluation of visuospatial constructional ability and visual memory.

¹³ Deckersbach T et al. Reliability and Validity of a Scoring System for Measuring Organizational Approach in the Complex Figure Test, *Journal of Clinical and Experimental Neuropsychology*, 2000, Vol. 22, No. 5, pp. 640-648

¹⁴ The Rey Auditory Verbal Learning Test is a neuropsychological assessment designed to evaluate verbal memory.

¹⁵ Schoenberg MR et al. Test performance and classification statistics for the Rey Auditory Verbal Learning Test in selected clinical samples *The Clinical Neuropsychologist*, 1998, Vol. 12, No. 1, pp. 43-55

attending AA [Alcoholics Anonymous]. On a record dated July 26, 2013 the patient's counseling was terminated after 4 weeks when he failed to attend scheduled sessions.

Medical Conditions

Attention deficit hyperactivity disorder (ADHD)

ADHD is not just associated with deficits in attention and susceptibility to distraction but also with impulsivity and impairments in motor inhibition, reaction time, visual-motor coordination, executive functioning, decision-making, and rule-governed behavior that interfere with functioning.¹⁶

Adolescents and young adults with ADHD are 2 to 4 times more likely to have been the driver in a motor vehicle accident, have higher rates of moving violations, and are more likely to have had their license revoked or suspended than peers without the illness.^{17,18,19,20} When involved in accidents, drivers diagnosed with ADHD are more likely to be the at-fault driver and tend to incur greater damage to their vehicles.²⁰ The large majority of these driving studies did not differentiate between subjects with ADHD treated with medication and those that were not using medication. Results of a recent meta-analysis indicate there may be a beneficial effect of methylphenidate (and other medications for ADHD) on driving performance but the effect size remains unclear; medication does not appear to fully negate the safety hazards associated with the illness. In fact, the Guide for Aviation Medical Examiners explicitly requires aviation medical examiners to defer medical certification for pilots who report ADHD or use of medications to treat it until the pilot has undergone extensive neuropsychological evaluation and review.^{21,22}

Depression

Major depressive disorder is characterized by depressed mood or the loss of interest or pleasure in nearly all activities. Additionally symptoms include changes in weight, sleep, and psychomotor activity; decreased energy, feeling of worthlessness or guilt; difficulty thinking, concentrating, or making decisions and may include thoughts of death or suicidal ideations.²³ Additionally, major depression itself is associated with

¹⁶ American Psychiatric Association. (2013). *Diagnostic and statistical manual of mental disorders* (5th ed.). Arlington, VA: American Psychiatric Publishing.

¹⁷ Barkley, RA et al. Driving-related risks and outcomes of attention deficit hyperactivity disorder in adolescents and young adults: A 3– 5 year follow-up survey. *Pediatrics* 1993;113: 212– 218.

¹⁸ Murphy, K, Barkley, RA. ADHD in adults: Comorbidities and adaptive impairments. *Comprehensive Psychiatry*, 1996;37: 393– 401.

¹⁹ Barkley, RA et al. Motor vehicle driving performance and risks in young adults with ADHD. *Pediatrics*, 1996;98: 1089–1095.

²⁰ Aduen PA, et al. Motor vehicle driving in high incidence psychiatric disability: comparison of drivers with ADHD, depression, and no known psychopathology. *J Psychiatr Res.* 2015; 64:59-66.

²¹ FAA Guide for Aviation Medical Examiners. Decision Considerations Disease Protocols - Attention Deficit/Hyperactivity Disorder: Specifications for Neuropsychological Evaluations for ADHD or ADD. http://www.faa.gov/about/office_org/headquarters_offices/avs/offices/aam/ame/guide/dec_cons/disease_prot/adhd/ Accessed 11/16/2016.

²² FAA Guide for Aviation Medical Examiners. Pharmaceuticals (Therapeutic Medications) Do Not Issue - Do Not Fly. https://www.faa.gov/about/office_org/headquarters_offices/avs/offices/aam/ame/guide/pharm/dni_dnf/ Accessed 10/21/2016.

²³ American Psychiatric Association. (2013). *Diagnostic and statistical manual of mental disorders* (5th ed.). Arlington, VA: American Psychiatric Publishing.

significant cognitive degradation, particularly in executive functioning.²⁴ The cognitive degradation may not improve even with remission of the depressed episode, and patients with severe disease are more significantly affected than those with fewer symptoms or episodes.^{25,26}

Additionally, depression is a disqualifying condition for pilot medical certification and according to the Guide for Aviation Medical Examiners; an aviation medical examiner should not issue a medical certificate to a depressed pilot. The FAA will consider a special issuance of a medical certificate for depression after 6 months of treatment if the applicant is clinically stable on one of four approved medications; fluoxetine is one of the medications but bupropion is not.²⁷

Diabetes

Diabetes is a group of diseases resulting in elevated blood glucose. There are two types of diabetes, type 1, where the body does not make insulin and type 2, where the body does not make or use insulin well enough. Type 1 diabetes requires treatment with insulin while type 2 diabetes can be treated with diet alone, or a number of different oral medications, but some patients may require insulin for glucose control. Normal fasting glucose levels range from about 65 to 99 mg/dl. Diabetes is defined as a fasting blood glucose greater than or equal to 126 mg/ml. Long-term, excessive blood glucose results in progressive damage to small blood vessels of multiple organs including the eyes, nerves, kidneys, and extremities eventually leading to blindness, numbness, kidney failure, and loss of limbs.²⁸

Hemoglobin A1C is a measure of how much glucose is bound to hemoglobin; it corresponds to the average blood glucose level and is a measure of diabetic control over several weeks. The target hemoglobin A1C level, representing good control, is less than 7%, which correlates to an average blood sugar of 154 mg/dl. Lowering A1C levels below 7% has been shown to reduce the incidences of diabetic complications.²⁹

Fibromyalgia

Fibromyalgia is a common cause of chronic pain characterized by widespread musculoskeletal pain, fatigue and often accompanied by cognitive and psychiatric disturbances.³⁰ The FAA advises AMEs to deny or defer issuance of a medical certificate to an applicant with a history of a neurological condition that may potentially incapacitate an individual. Additionally, the advice states that chronic conditions may

²⁴ Snyder H. Major depressive disorder is associated with broad impairments on neuropsychological measures of executive function: A meta-analysis and review. *Psychol Bull*, 2013. 139(1): p. 81-132.

²⁵ Nakano Y, et al. Executive dysfunction in medicated, remitted state of major depression. *J Affect Disord*, 2008. 111(1): p. 46-51.

²⁶ Paelecke-Habermann Y, et al. Attention and executive functions in remitted major depression patients. *J Affect Disord*, 2005. 89(1-3): p. 125-135.

²⁷ FAA Guide for Aviation Medical Examiners, Item 47. Psychiatric Conditions - Use of Antidepressant Medications.

https://www.faa.gov/about/office_org/headquarters_offices/avs/offices/aam/ame/guide/app_process/exam_tech/item_47/amd/antidepressants/ Accessed 11/16/2016

²⁸ American Diabetes Association, Statistics about Diabetes. Prevalence. <http://www.diabetes.org/diabetes-basics/statistics/> Accessed 11/16/2016

²⁹ American Diabetes Association, Standards of Medical Care in Diabetes—2016, Volume 39, Supplement 1, January 2016 http://care.diabetesjournals.org/highwire/filestream/5646/field_highwire_adjunct_files/0/2016-Standards-of-Care.pdf Accessed 11/16/2016

³⁰ Goldenberg DL Clinical manifestations and diagnosis of fibromyalgia in adults, (2016) Editors Schur P, Romain P. UpToDate, Waltham, MA

be incompatible with safety in aircraft operation because of long-term unpredictability, severe neurologic deficit, or psychological impairment.³¹

Autopsy

The pathologist at Central Texas Autopsy determined the cause of death for the pilot was blunt force injuries and thermal burns and the manner of death was accident. The report described multiple blunt force chest, abdomen, and pelvic injuries, with thermal injuries of upper and lower extremities but no obvious evidence of electrical burns or inhalation of products of combustion. The autopsy did not identify any significant natural disease.

Toxicology

The medical examiner collected femoral blood specimens that were tested by a NMS Forensic Toxicology Laboratory. Additionally, the NTSB requested the FAA Bioaeronautical Research Laboratory conduct further forensic toxicology testing. The FAA laboratory received adequate solid tissue specimens but testing of blood was limited by a small specimen volume. Finally, the FAA clinical testing documented the hemoglobin A1C was 7.3% and 38 mg/dl glucose was detected in urine.³² The results of NMS and FAA testing are listed in Table 4

³¹ FAA Guide for Aviation Medical Examiners. Decision Considerations - Aerospace Medical Dispositions Item 46. Neurologic.

http://www.faa.gov/about/office_org/headquarters_offices/avs/offices/aam/ame/guide/app_process/exam_tech/item46/amd/ Accessed 11/16/2016

³² According to the FAA forensic toxicology report, postmortem urine levels above 100 mg/dL are considered abnormal. Hemoglobin A1C is analyzed using a latex immunoagglutination inhibition methodology. Hemoglobin A1C blood levels above 6% are considered abnormal.

Table 4 - NMS and FAA Forensic Toxicology Results

Parent Compound	Identified Substance	Tissue	Result	Units	Lab
Acetaminophen	Acetaminophen	Urine	32.72	mcg/mL	FAA
Bupropion	Bupropion	Blood	62	ng/mL	NMS
	Hydroxybupropion*	Blood	340	ng/mL	NMS
Carbon Monoxide	Carboxyhemoglobin	Blood	Negative [£]	Percent	NMS
Caffeine	Caffeine	Blood	Positive	mcg/mL	NMS
Cyclobenzaprine	Cyclobenzaprine	Blood	20	ng/mL	NMS
	Norcyclobenzaprine*	Liver	Positive	none	FAA
	Norcyclobenzaprine*	Blood	Positive	none	FAA
Dextromethorphan	Dextro/Levo-methorphan	Blood	100	ng/mL	NMS
	Dextromethorphan	Lung	Positive	none	FAA
	Dextromethorphan	Liver	Positive	none	FAA
Diazepam[∨]	Diazepam	Blood	130	ng/mL	NMS
	Nordiazepam*	Blood	180	ng/mL	NMS
	Nordiazepam*	Lung	47	ng/g	FAA
	Diazepam	Lung	30	ng/g	FAA
	Diazepam	Liver	87	ng/g	FAA
Diphenhydramine	Diphenhydramine	Blood	65	ng/mL	NMS
	Diphenhydramine	Lung	Positive	none	FAA
	Diphenhydramine	Liver	Positive	none	FAA
Fluoxetine	Fluoxetine	Blood	500	ng/mL	NMS
	Fluoxetine	Blood	298	ng/mL	FAA
	Fluoxetine	Liver	40.433	mcg/g	FAA
	Norfluoxetine*	Blood	96	ng/mL	NMS
	Norfluoxetine*	Liver	Positive	none	FAA
Methylphenidate	Methylphenidate	Blood	5.0	ng/mL	NMS
	Methylphenidate	Lung	Positive	none	FAA
	Ritalinic Acid*	Blood	180	ng/mL	NMS
Oxycodone	Oxycodone – Free	Blood	8.1	ng/mL	NMS
	Oxycodone	Blood	Positive	none	FAA
	Oxycodone	Urine	977	ng/mL	FAA
	Oxymorphone*	Urine	Positive	none	FAA

* Indicates a metabolite of the parent compound

£ NMS laboratory reporting limit is 5 percent saturation

∨ Potentially impairing compounds have bold letters

Description of Detected Medications and Drug Interactions

Acetaminophen reduces pain and fever it is used alone and in combination in many prescription and over-the-counter products and is commonly recognized by the trade name Tylenol.³³

Bupropion is an antidepressant used to treat depression and help patients quit smoking, often marketed with the names Wellbutrin and Zyban. It carries a warning of increased risk of seizures.³⁴ Bupropion's half-life ranges from 4 to 24 hours; it is transformed to a less active metabolite hydroxybupropion. In depressed patients, the maximum improvement in symptoms occurred at plasma levels between 50 and 100 ng/mL.³⁵ The FAA will consider a special issuance of a medical certificate for depression after 6 months of treatment if the applicant is clinically stable on one of four approved medications; bupropion is not one of these medications.³⁶

Caffeine is a common central nervous system (CNS) stimulant found in coffee and tea.³⁷

Cyclobenzaprine is a prescription muscle relaxant marketed under various names including Amrix and Flexmib. It carries the warning “[cyclobenzaprine], especially when used with alcohol or other CNS depressants, may impair mental and/or physical abilities required for performance of hazardous tasks, such as operating machinery or driving a motor vehicle.”³⁸ A single 10 mg dose of cyclobenzaprine yielded an average plasma level of 9 ng/mL. Its half-life is 20 to 40 hours and when given three times a day for a week resulted in a peak plasma level averaging 26 ng/mL.³⁹ Diphenhydramine, oxycodone and diazepam are CNS depressants and may enhance the adverse toxic effects of this medication.⁴⁰

Dextromethorphan is a cough suppressant found in many over the counter cold and flu preparations including Robitussin and Delsym. The therapeutic range is considered to be between 2 and 40 ng/mL with a half-life ranging from 3.2 to 3.6 hours. Toxic effects including increased sedation can be seen at levels around 100 ng/mL.⁴¹

³³ FAA Forensic Toxicology Drug Information. Acetaminophen

<http://jag.cami.jccbi.gov/toxicology/DrugDetail.asp?did=2> Accessed 11/16/2016

³⁴ National Institutes of Health. US National Library of Medicine. DailyMed. WELLBUTRIN XL- bupropion hydrochloride tablet <https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=a435da9d-f6e8-4ddc-897d-8cd2bf777b21> Accessed 11/16/2016.

³⁵ Baselt RC Disposition of Toxic Drugs and Chemicals in Man, 10th Edition. Bupropion. Pages 300-303 Copyright 2014, Biomedical Publications, Seal Beach, California.

³⁶ FAA Guide for Aviation Medical Examiners, Item 47. Psychiatric Conditions - Use of Antidepressant Medications.

https://www.faa.gov/about/office_org/headquarters_offices/avs/offices/aam/ame/guide/app_process/exam_tech/item_47/amd/antidepressants/ Accessed 11/16/2016

³⁷ U.S. National Library Of Medicine, MedlinePlus, Caffeine <https://medlineplus.gov/caffeine.html> Accessed 11/16/2016

³⁸ National Institutes of Health. US National Library of Medicine. DailyMed. FEXMID- cyclobenzaprine hydrochloride tablet. <https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=ff573a22-261d-4096-ad47-03e9bcebf331> Accessed 11/16/2016

³⁹ Baselt RC Disposition of Toxic Drugs and Chemicals in Man, 10th Edition. Cyclobenzaprine pages 542-544 Copyright 2014, Biomedical Publications, Seal Beach, California.

⁴⁰ Lexicomp Online®, Lexi-Comp Online™ Interaction Analysis, Hudson, Ohio: Lexi-Comp, Inc.; Accessed 11/16/2016.

⁴¹ FAA Forensic Toxicology Drug Information. Dextromethorphan

<http://jag.cami.jccbi.gov/toxicology/DrugDetail.asp?did=42> Accessed 11/16/2016

Diazepam is a long acting sedating benzodiazepine, a Schedule IV controlled substance, available by prescription and used in the treatment of anxiety and painful muscle spasms; it is commonly marketed with the name Valium.⁴² Nordiazepam is a psychoactive metabolites of diazepam. Therapeutic diazepam blood concentrations typically range from 100 - 1000 ng/mL and the half-life ranges from 21 to 37 hours. Additionally, in a limited study of four healthy men following a single 10 mg dose the peak average diazepam level was 148 ng/mL at one hour declining to 37 ng/mL by 24 hours.⁴³ The performance effects of diazepam have been demonstrated in laboratory studies that showed a single doses of diazepam (5-20 mg) are capable of causing significant performance decrements, with maximal effect occurring at approximately 2 hour post dose, and lasting up to at least 3-4 hours. Decreases in divided attention, increases in lane travel, slowed reaction time (auditory and visual), increased braking time, decreased eye-hand coordination, and impairment of tracking, vigilance, information retrieval, psychomotor and cognitive skills have been recorded. Lengthened reaction times have been observed up to 9.5 hours post dose. Reduced concentration, impaired speech patterns and content, and amnesia can also be produced, and diazepam may produce some effects that may last for days.⁴⁴ Cyclobenzaprine, diphenhydramine and oxycodone are CNS depressants and may enhance the adverse toxic effects of this medication.⁴⁵

Diphenhydramine is a sedating antihistamine used to treat allergy symptoms and as a sleep aid. It is available over the counter under the trade names Benadryl and Unisom. Diphenhydramine carries the following FDA warning: may impair mental and/or physical ability required for the performance of potentially hazardous tasks (e.g., driving, operating heavy machinery). The therapeutic range for diphenhydramine is about 25 to 112 ng/ml.⁴⁶ Blood concentrations following a single dose of 50 mg diphenhydramine in 10 healthy adults produced an average peak plasma concentration of 66 ng/mL at 2.3 hours.⁴⁷ Compared to other antihistamines, diphenhydramine causes marked sedation; this is the rationale for its use as a sleep aid. Altered mood and impaired cognitive and psychomotor performance may also be observed. In fact, in a driving simulator study, a single 50 mg dose of diphenhydramine impaired driving ability more than a blood alcohol concentration of 0.100.⁴⁸ Cyclobenzaprine, oxycodone and diazepam are CNS depressants and may enhance the adverse toxic effects of this medication.⁴⁹

⁴² National Institutes of Health. US National Library of Medicine. DailyMed. Diazepam tablets. <https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=ab4e5d9c-64fa-4bab-9e7f-ed02109568af> Accessed 10/21/2016.

⁴³ Baselt RC Disposition of Toxic Drugs and Chemicals in Man, 10th Edition. Diazepam 618-621 Copyright 2014, Biomedical Publications, Seal Beach, California.

⁴⁴ National Highway Traffic Safety Administration, Drugs and Human Performance Fact Sheets, Diazepam. <http://www.nhtsa.gov/people/injury/research/job185drugs/diazepam.htm> Accessed 09/21/2016

⁴⁵ Lexicomp Online, Lexi-Comp Online™ Interaction Analysis, Hudson, Ohio: Lexi-Comp, Inc.; Accessed 11/16/2016

⁴⁶ FAA, Civil Aerospace Medical Institute. Toxicology Drug Information: Diphenhydramine. <http://jag.cami.jccbi.gov/toxicology/DrugDetail.asp?did=50> Accessed 10/21/2016.

⁴⁷ Baselt RC Disposition of Toxic Drugs and Chemicals in Man, 10th Edition. Diphenhydramine. Pages 684-687 Copyright 2014, Biomedical Publications, Seal Beach, California.

⁴⁸ Weiler JM, et al. Effects of fexofenadine, diphenhydramine, and alcohol on driving performance. A randomized, placebo-controlled trial in the Iowa Driving Simulator. *Ann Intern Med.* 2000;132(5): 354-63.

⁴⁹ Lexicomp Online®, Lexi-Comp Online™ Interaction Analysis, Hudson, Ohio: Lexi-Comp, Inc.; Accessed 11/16/2016.

Fluoxetine is a prescription antidepressant medication marketed under the trade name Prozac. Norfluoxetine is the active metabolite of fluoxetine. Steady state plasma drug levels in patients taking 20 to 60 mg daily averaged 109 ng/ml and ranged from 18 to 466 ng/mL, the half-life of the medication ranges from 1 to 3 days.⁵⁰ The FAA will consider a special issuance of a medical certificate for depression after 6 months of treatment if the applicant is clinically stable and using only one approved treatment medication. Fluoxetine is one of the FAA approved antidepressant medications.⁵¹ Additionally, while fluoxetine at therapeutic levels is generally not impairing; diphenhydramine, oxycodone and diazepam are CNS depressants that may enhance the adverse/toxic effect of fluoxetine. Specifically, the risk of psychomotor impairment may be enhanced.⁵²

Methylphenidate is a Schedule II stimulant used to treat narcolepsy and attention deficit hyperactivity disorder. It is marketed under various names including Ritalin and Concerta and carries a number of warnings including: "...should be given cautiously to patients with a history of drug dependence or alcoholism. Chronic abusive use can lead to marked tolerance and psychological dependence with varying degrees of abnormal behavior."⁵³ Methylphenidate's half-life ranges from 1.4 to 4.2 hours and is converted to the inactive metabolite ritalinic acid. Typical therapeutic plasma levels are dose dependent and range from 5.9 to 9.9 ng/mL.⁵⁴

Oxycodone is a Schedule II synthetic narcotic pain medication marketed under various names including Percocet and Oxycontin. Plasma concentrations following administration of normal release oxycodone (4.5 mg oxycodone hydrochloride plus 0.38 mg terephthalate) averaged 18 ng/mL (range, 9 -37) at 1 hour, 16 ng/mL at 2 hours, 9 ng/ml at 4 hours and 5 ng/mL at 8 hours. The half-life is reported to be 3 to 6 hours.⁵⁵ It carries a number of warnings including "Hypotension and profound sedation, coma, or respiratory depression may result if [oxycodone] is used concomitantly with other CNS depressants (e.g., sedatives, anxiolytics, hypnotics, neuroleptics, other opioids). Additionally, warnings state the medication "...may impair the mental or physical abilities needed to perform potentially hazardous activities such as driving a car or operating machinery. Warn patients not to drive or operate dangerous machinery unless they are tolerant to the effects of [oxycodone] and know how they will react to the medication."⁵⁶ Cyclobenzaprine,

⁵⁰ Baselt RC Disposition of Toxic Drugs and Chemicals in Man, 10th Edition. Fluoxetine. Pages 881-884 Copyright 2014, Biomedical Publications, Seal Beach, California.

⁵¹ FAA Guide for Aviation Medical Examiners, Item 47. Psychiatric Conditions - Use of Antidepressant Medications.

https://www.faa.gov/about/office_org/headquarters_offices/avs/offices/aam/ame/guide/app_process/exam_tech/item_47/amd/antidepressants/ Accessed 11/16/2016

⁵² Lexicomp Online®, Lexi-Comp Online™ Interaction Analysis, Hudson, Ohio: Lexi-Comp, Inc.; Accessed 11/16/2016.

⁵³ National Institutes of Health. US National Library of Medicine. DailyMed. CONCERTA- methylphenidate hydrochloride tablet. <https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=1a88218c-5b18-4220-8f56-526de1a276cd> Accessed 11/16/2016

⁵⁴ Baselt RC Disposition of Toxic Drugs and Chemicals in Man, 10th Edition. Methylphenidate. Pages 1335-1337 Copyright 2014, Biomedical Publications, Seal Beach, California.

⁵⁵ Baselt RC Disposition of Toxic Drugs and Chemicals in Man, 10th Edition. Oxycodone, pages 1528-1531 Copyright 2014, Biomedical Publications, Seal Beach, California.

⁵⁶ National Institutes of Health. US National Library of Medicine. DailyMed. OXYCONTIN- oxycodone hydrochloride tablet. <https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=bfdfe235-d717-4855-a3c8-a13d26dadede> Accessed 11/16/2016

diphenhydramine and diazepam are CNS depressants and may enhance the adverse toxic effects of this medication.⁵⁷

E. SUMMARY OF FINDINGS

The accident pilot was not required to have a medical certificate or driver's license to operate as a commercial balloon pilot with paying passengers. He last held a third class medical certificate in 1996, and had a revoked Missouri driver's license. He had a history of multiple alcohol and drug related traffic and non-traffic offenses, resulting in convictions and two subsequent periods of incarceration. He had been diagnosed with alcohol dependence in remission, although various sources differed on the length of sobriety. In addition, he had high blood pressure and elevated cholesterol which were treated with losartan and simvastatin respectively. Additionally, he had diabetes treated with the oral medication metformin and injectable insulin; major depressive disorder treated with bupropion, and fluoxetine; attention deficit disorder treated with methylphenidate; insomnia treated with zolpidem; fibromyalgia treated with cyclobenzaprine, piroxicam, and pregabalin; and chronic back pain and muscle spasm treated with oxycodone and diazepam. Toxicological testing detected evidence of use of a combination of caffeine, diazepam, oxycodone, bupropion, methylphenidate, diphenhydramine, cyclobenzaprine, fluoxetine, and dextromethorphan.

⁵⁷ Lexicomp Online®, Lexi-Comp Online™ Interaction Analysis, Hudson, Ohio: Lexi-Comp, Inc.; Accessed 11/16/2016.

Attachment 1 - FAA Alcohol Memorandum



Federal Aviation Administration
 Security and Hazardous Material Organization
 Mike Monroney Aeronautical Center

Memorandum

Date: July 22, 2013

From: Special Agent, [REDACTED], [REDACTED]

To: Civil Aerospace Medical Institute, AAM-313

Subject: INFORMATION: Alcohol Related Motor Vehicle Action

The following medical record ID is forwarded for your action as deemed appropriate:

Name	[REDACTED]	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	Address matches DIWS record:
Last 4 of SSN	[REDACTED]		
MID	[REDACTED]		

Date	Type of Offense	Action	State
August 30, 1985	Administrative Alcohol	Suspension	MO
February 08, 1997	Chemical Refusal*	Revocation	MO
December 07, 1998	Excessive Blood Alcohol*	Conviction	MO
December 11, 1999	Chemical Refusal**	Revocation	MO
September 27, 2002	Driving While Intoxicated**	Conviction	MO
April 1, 2000	Chemical Refusal***	Revocation	MO
September 27, 2002	Driving While Intoxicated***	Conviction	MO
June 16, 2007	Chemical Refusal****	Revocation	MO
May 25, 2010	Driving While Intoxicated****	Conviction	MO

**The MVAs are related to the same offense.

The following action has been initiated by AMC-700.

<input type="checkbox"/> No Enforcement Action - documented on medical application within 60 days	<input type="checkbox"/> 61.15(e)
<input type="checkbox"/> No Enforcement Action - MVA(s) before program - records not available	<input type="checkbox"/> 61.15(d)(2)
<input checked="" type="checkbox"/> No Enforcement Action - Notification Letter	<input type="checkbox"/> 67.403A1
<input type="checkbox"/> No Enforcement Action - Notification Letter - MVA(s) have been expunged.	<input type="checkbox"/> 67.403C1
<input type="checkbox"/> No Enforcement Action - Does not detail motor vehicle action appropriately	<input type="checkbox"/> Administrative Action

EIR Number 2013AC750185

[REDACTED]